bioBoaVista	TECHNICAL DATA SHEET	Revision 6.0

MOLECULAR TRANSPORT MEDIUM (MTM)
FDA K233324
ANVISA #80429030007

Presentation
Vial with 2ml or 3ml.

Sterilization method
MTM is not claimed to be sterile nor is it intended to be sterilized by the end user. These vials are single use devices. The manufacturing process includes sterilization of the polypropylene tubes prior to being filled by ethylene oxide (EO). Dispensing

Application
The MTM is intended for the stabilization, transportation, and direct lysis of infectious unprocessed nasopharyngeal samples suspected of containing SARS-CoV-2 virus.

Principle
The formulation of the MTM includes guanidine-free inactivation buffer, salts, a buffer to maintain a neutral pH, and distilled water. The MTM maintains the integrity of SARS-CoV-2 viral nucleic acid when properly stored.

How to use
1. Open the package of the indicated swab and extract it.
2. Label the sample.
3. Collect the sample. During sampling, the swab end (tip) shall only meet the suspected infection, to reduce contamination risks.
4. After patient sampling, immediately place the tip of the swab into the tube containing MTM.
5. Break the swab off into tubes of MTM by aligning the red-marked breakpoint with the upper edge of the tube and bend until the swab breaks off at the mark, leaving the swab tip in the transport tube. Discard the stick and recap the transport tube containing the swab sample.
6. Standard operating protocols for clinical specimen handling and preservation should be followed after the sample collection. The transport tube containing the swab with SARS-CoV-2 nucleic acid can be stored up to 21 days at 15-35°C.
7. Proceed with SARS-CoV-2 nucleic acid extraction after at least 5 minutes of sample incubation in MTM.
8. Specimens collected for clinical investigations should be collected and handled following published manuals and guidelines.
9. Specific requirements for the shipment and handling of specimens should be in full compliance with state and federal regulations. Shipping of specimens within medical institutions should comply with the internal guidelines of the institution.

Quality Control

Test	Result
Appearance	Liquid medium, colorless, clear, may contain slight precipitate
pH at 25°C	8.0 ± 1.0

Results interpretation
Detection of the target genetic material should be in accordance with official compendia or internal laboratory methodology.

Precautions and special care
1. For in vitro diagnostic use only.
2. For prescription use only.
3. To be handled by trained personnel only.
4. Instructions must be followed carefully. The manufacturer cannot be held responsible for any unauthorized or unqualified use of the product.
5. Nasopharyngeal swab collection should be done following standard technique by a trained health care professional.
6. Not intended for therapeutic use.
7. This product is for singe use only; reuse may cause inaccurate results.
8. Do not re-pack.
9. Not suitable for any other application than intended use.
10. The use of this product in association with a rapid diagnostic kit or with diagnostics instrumentation should be previously validated by the user.
11. Condition, timing, and volume of specimen collected for clinical investigations are significant variables in obtaining reliable results. Follow recommended guidelines for specimen collection.
12. Avoid swab contact with the exterior of the transport tube. Check the package before using it. If damaged, do not use it.
13. Do not use swab if the swab is visibly damaged, (i.e., if the swab tip or swab shaft is broken).
14. Do not use calcium alginate swabs or swabs with wooden shafts for collection.
15. The vial container may become brittle at cold temperatures and may crack if dropped. Handle with care. 16. Do not use excessive force, pressure, or bending when collecting swab samples from patients as this may result in accidental breakage of the swab shaft. The swab shaft features a molded breakpoint designed for the intentional breakage of the swab into a transport tube.
17. It must be assumed that all specimens contain infectious microorganisms; therefore all specimens must be handled with appropriate precautions.
18. In the laboratory, wear protective gloves and other protection commensurate with universal precautions when handling clinical specimens. Observe biosafety recommendations when handling or analyzing patient samples.
19. Dispose of used swabs as well as any other contaminated disposable materials following procedures for infectious or

A.L.B. Luz – 437 Um Street, Jd. Nova Espírito Santo, CEP 13273-200, Valinhos, São Paulo, Brazil
+55 (19) 3849-7499
contato@bioboavista.com.br
www.bioboavista.com.br

potentially infectious products. Each laboratory is responsible for handling waste and effluents produced according to their nature and degree of hazardousness, treating, and disposing of them (or having them treated and disposed of) per applicable regulations.Product intended for in vitro diagnostic use only.

Restricted for use by professionals. Do not inhale or ingest.

Do not use the product beyond the expiration date, with signs of contamination, or if it has changed color. In the presence of contamination, the product should be immediately discarded.

Do not use the product if the packaging is damaged or tampered with.

Storage

Store the product in a cool, dry place. The storage temperature for the vial with reagent is 15-35°C. Do not overheat or freeze prior to use.

Shelf-life

18 months from the date of manufacture.

Disposal of the product

After use, the product must be handled at the generating unit before environmentally appropriate final disposal, in accordance with official regulations.

Quality Guarantee

bioBoaVista guarantees the quality of its products as long as they are used according to their respective instructions and in accordance with national and international references. bioBoaVista does not take responsibility for the use of its products for purposes other than those described and approved by the company. All clinical diagnoses should be analyzed in conjunction with clinical evidence and not solely based on laboratory results.

References

FDA U.S. Food & Drug Administration. 510(k) Substantial Equivalence Determination. Decision Summary. 510(k) Number K233324.

A.L.B. Luz – Rua Um, 437, Jd. Nova Espírito Santo, CEP 13273-200, Valinhos - SP
19 3849-7499
contato@bioboavista.com.br
www.bioboavista.com.br